

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 19390.0003 U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 09/936722
INTERNATIONAL APPLICATION NO. PCT/SE00/00359	INTERNATIONAL FILING DATE 24 February 2000	PRIORITY DATE CLAIMED 18 March 1999
TITLE OF INVENTION METHOD, ARRANGEMENT AND USE FOR APPLYING A SPACER TO AN IMPLANT BY MEANS OF A SCREW		
APPLICANT(S) FOR DO/EO/US Lars Jörneus		
<p>Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"> <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371 <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. § 371. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. <input checked="" type="checkbox"/> A copy of the International Application as published (35 U.S.C. 371(c)(2)) WO 00/54697 <ol style="list-style-type: none"> <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). <input type="checkbox"/> has been transmitted by the International Bureau. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)). <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau). <input type="checkbox"/> have been transmitted by the International Bureau. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. <input type="checkbox"/> have not been made and will not be made. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). <input type="checkbox"/> A translation of the Annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). <p>Items 11. to 16. below concern other document(s) or information included:</p> <ol style="list-style-type: none"> <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98, PTO-1449, 7 references. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. <input type="checkbox"/> A substitute specification. <input type="checkbox"/> A change of power of attorney and/or address letter <input checked="" type="checkbox"/> Other items or information: PCT/ISA/210 PCT/IB/308 PCT/IPEA/409 PCT/RO/101 		

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[x] The following fees are submitted:

531 Rec'd PCT.

CALCULATIONS
18 SEP 2001**Basic National Fee (37 CFR 1.492(a)(1)-(5)):**

Search Report has been prepared by the EPO or JPO.....\$860.00

International preliminary examination fee paid to USPTO (37 CFR 1.482)\$690.00

No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)).....\$760.00

Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....\$1,000.00

International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4).....\$100.00

ENTER APPROPRIATE BASIC FEE AMOUNT = \$1,000.00Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).

\$130.00

Claims	Number Filed	Number	Rate		
Total Claims	24 - 20 =	4	X \$18.00	\$72.00	
Independent Claims	4 - 3 =	1	X \$80.00	\$80.00	
Multiple dependent claim(s)(if applicable)			+ \$270.00	\$0.00	

TOTAL OF ABOVE CALCULATIONS = \$1,282.00

Reduction by 1/2 for filing by small entity, if applicable.

\$

SUBTOTAL = \$1,282.00Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).

\$

TOTAL NATIONAL FEE = \$1,282.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +

\$

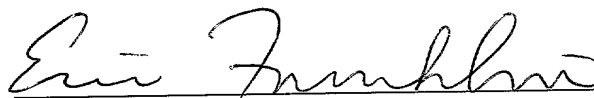
TOTAL FEES ENCLOSED = \$0.00Amount to be:
refunded \$

charged \$1,282.00

a. ☐ A check in the amount of \$_____ to cover the above fees is enclosed.b. [x] Please charge my Deposit Account No. 19-5127, Order No. 19390.0003 in the amount of \$ **1,282.00** to cover the above fees.
A duplicate copy of this sheet is enclosed.c. [x] The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-5127. A duplicate copy of this sheet is enclosed.**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status****SEND ALL CORRESPONDENCE TO:****Edward A. Pennington****Swidler Berlin Shereff Friedman, LLP**

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SIGNATURE

Eric J. Franklin

NAME

37,134

REGISTRATION NUMBER

09/936722

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: :
: Atty Docket: 19390.0003
Lars Jörneus :
: Application No. -- Corresp. to PCT/SE00/00359 : Art Unit: --
: Filed: September 18, 2001 : Examiner: --

For: METHOD, ARRANGEMENT AND USE FOR APPLYING A SPACER TO AN
IMPLANT BY MEANS OF A SCREW

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination, please amend the above-identified application as follows:

In the Claims:

Please amend the claims as follows:

Clean copy of amended claims

7. Arrangement according to Patent Claim 5, characterized in that the holder or holder part (1b) is provided with a first recess (1f) for the screw head and a second recess (1e) for one or more securing parts (1g) on the spacer, and the holder can be applied on the securing part or securing parts and the screw head and secures the spacer and the screw by means of elasticity or resilience in the wall-supporting material of the first and second recesses.

8. Arrangement according to Patent Claim 5, characterized in that the holder consists of or comprises an elongate part (1a, 1b) made of plastic or equivalent material.

9. Arrangement according to Patent Claim 5, characterized in that the holder is comparatively easily separable from the spacer and the screw, in their position applied in or firmly screwed to the implant, by means of a withdrawal movement which essentially coincides with the longitudinal direction (1h) of the implant or rotating movement which is distinct from the screwing movement.

10. Arrangement according to Patent Claim 5, characterized in that the spacer is provided with an annular bearing surface (2a) without internal guide surfaces, for example guide surfaces in the form of squares or hexagonal surfaces.

11. Arrangement according to Patent Claim 5, characterized in that the holder and its attachment to the spacer and the screw are arranged to permit a first anchoring contact between the top surface of the implant and the bearing surface of the spacer which eliminates the risk of loosening of the implant in the bone (5), and, after the holder has been removed, the screw can be tightened to obtain a second anchoring contact which is effected with a force which considerably exceeds the force for the first anchoring contact.

13. Arrangement according to Patent Claim 5, characterized in that the thread of the screw is made of relatively strong material and/or is coated with a friction-reducing coating for the purpose of improving the anchoring stress between spacer, screw and implant.

14. Arrangement according to Patent Claim 5, characterized in that the thread diameter of the screw is substantially less than the diameter of the bearing surface and is, for example, half the last-mentioned diameter.

18. Arrangement according to Patent Claim 16, characterized in that the spacer and the screw head assume rotationally fixed positions in the holder by virtue of the fact that the latter is made of resilient and/or elastic material at least at the said recess, and the holder with resilient and/or elastic function cooperates with the spacer and the screw head.

19. Arrangement according to Patent Claim 16, characterized in that the rotationally fixed

attachment is also effected by a snap-in function and in that, for example, the spacer is designed with nibs and/or indents (2f, 2g) for the said snap-in function.

20. Arrangement according to Patent Claim 16, characterized in that, when the spacer and screw are positioned on the implant, the holder can be separated from the spacer and the screw head for longitudinal displacement in the longitudinal direction of the implant and/or a tilting movement.

21. Arrangement according to Patent Claim 16, characterized in that the holder, the spacer and the screw form a rotationally fixed unit, by means of which the thread of the screw can be screwed into the thread of the implant by screwing movements.

24. Use according to Patent Claim 22, characterized in that the holder is used for transmitting manual rotation movements to the screw as the latter is screwed into the implant.

Amended claims

7. (Amended) Arrangement according to Patent Claim 5 [or 6], characterized in that the holder or holder part (1b) is provided with a first recess (1f) for the screw head and a second recess (1e) for one or more securing parts (1g) on the spacer, and the holder can be applied on the securing part or securing parts and the screw head and secures the spacer and the screw by means of elasticity or resilience in the wall-supporting material of the first and second recesses.

8. (Amended) Arrangement according to [any of Patent Claims 5 to 7] Patent Claim 5, characterized in that the holder consists of or comprises an elongate part (1a, 1b) made of plastic or equivalent material.

9. (Amended) Arrangement according to [any of Patent Claims 5 to 8] Patent Claim 5, characterized in that the holder is comparatively easily separable from the spacer and the screw, in their position applied in or firmly screwed to the implant, by means of a withdrawal movement which essentially coincides with the longitudinal direction (1h) of the implant or

rotating movement which is distinct from the screwing movement.

10. (Amended) Arrangement according to [any of Patent Claims 5 to 9] Patent Claim 5, characterized in that the spacer is provided with an annular bearing surface (2a) without internal guide surfaces, for example guide surfaces in the form of squares or hexagonal surfaces.

11. (Amended) Arrangement according to [any of Patent Claims 5 to 10] Patent Claim 5, characterized in that the holder and its attachment to the spacer and the screw are arranged to permit a first anchoring contact between the top surface of the implant and the bearing surface of the spacer which eliminates the risk of loosening of the implant in the bone (5), and, after the holder has been removed, the screw can be tightened to obtain a second anchoring contact which is effected with a force which considerably exceeds the force for the first anchoring contact.

13. (Amended) Arrangement according to [any of Patent Claims 5 to 12] Patent Claim 5, characterized in that the thread of the screw is made of relatively strong material and/or is coated with a friction-reducing coating for the purpose of improving the anchoring stress between spacer, screw and implant.

14. (Amended) Arrangement according to [any of Patent Claims 5 to 13] Patent Claim 5, characterized in that the thread diameter of the screw is substantially less than the diameter of the bearing surface and is, for example, half the last-mentioned diameter.

18. (Amended) Arrangement according to Patent Claim 16 [or 17], characterized in that the spacer and the screw head assume rotationally fixed positions in the holder by virtue of the fact that the latter is made of resilient and/or elastic material at least at the said recess, and the holder with resilient and/or elastic function cooperates with the spacer and the screw head.

19. (Amended) Arrangement according to Patent Claim 16, [17 or 18,] characterized in that the rotationally fixed attachment is also effected by a snap-in function and in that, for example, the spacer is designed with nibs and/or indents (2f, 2g) for the said snap-in function.

20. (Amended) Arrangement according to [any of Patent Claims 16 to 19] Patent Claim 16, characterized in that, when the spacer and screw are positioned on the implant, the holder can be separated from the spacer and the screw head for longitudinal displacement in the longitudinal direction of the implant and/or a tilting movement.

21. (Amended) Arrangement according to [any of Patent Claims 16 to 20] Patent Claim 16, characterized in that the holder, the spacer and the screw form a rotationally fixed unit, by means of which the thread of the screw can be screwed into the thread of the implant by screwing movements.

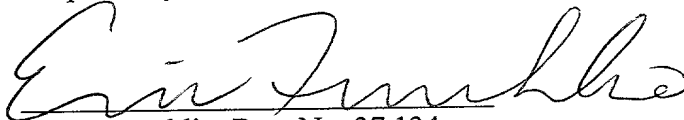
24. (Amended) Use according to Patent Claim 22 [or 23], characterized in that the holder is used for transmitting manual rotation movements to the screw as the latter is screwed into the implant.

Remarks

Applicants have amended the claims to eliminate multiple dependencies to reduce the filing fee.

Date: September 18, 2001

Respectfully submitted,



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TITLE

- 5 Method, arrangement and use for applying a spacer to an implant by means of a screw

10 The present invention relates to, inter alia, a method for securing a spacer to a firmly integrated implant, preferably in the jaw bone, by means of a holder and with the aid of a screw. The threaded part of the screw will extend through a recess in the spacer so that its thread cooperates with the thread of the implant. The screw head can moreover cooperate with a
15 tightening and locking surface in the spacer, which also has a bearing surface which can cooperate with a top surface of the implant. The invention also relates to an arrangement for application of this method. The invention relates in addition to the use of the holder
20 for securing a spacer in an implant by means of a screw.

After the implant has become firmly integrated in the bone, which normally takes 3 to 6 months after fitting the fixture or implant, a spacer is attached.
25 In this connection, an incision is made through the gum so that the upper surface of the implant is exposed. Upon attachment of the spacer, which is also called the spacer element, the latter is screwed securely to the implant or fixture. The spacers which are normally used
30 here are made up of an essentially cylindrical component which is to be screwed securely with a loose, separate screw. In the majority of cases, the spacer has an internal hexagon which is intended to match a corresponding external hexagon on the upper part of the
35 implant. There are also spacer designs in which the actual spacer body and the screw have been integrated to form one unit. However, it is advantageous to be able to use screw and spacer as two separate units. The tightening of the screw can then be improved by virtue

of the fact that the frictional torque acting on the screw head is reduced because the contact radius of the screw head is less compared to the case of using separately integrated spacer and screw. In addition, when the screw and spacer form different units, they can be made of different materials. The spacer is preferably made of a tissue-compatible material, for example titanium or a ceramic material. The screw can be made of stronger material and can be coated with a friction-reducing coating so as to obtain an improved prestressing of the screw connection. An alternative here, or complement, is to choose a screw material which itself affords low friction between the thread of the screw and the corresponding internal threading of the implant. Such material can, for example, include certain gold alloys.

In purely general terms, it is relatively difficult to handle small spacer and screw components in or around the oral cavity, for lack of space among other reasons. Various attempts have been made to make handling and securing of spacer and screw easier. For example, a special counterstay has been used which is arranged on the spacer at the same time as a screwdriver is engaged in the groove of the screw head. There are also examples of so-called pre-fitted disposable spacer holders which consist of two mutually movable parts, one of which engages round the screw and the other round the spacer.

In connection with the said known prior art, reference may be made to US Patent Specifications 5,145,371, 5,322,443, 5,462,436, 5,437,550 and 5,692,904.

There is in general a great need to be able to handle small spacer and screw components in accordance with the above. In this context, it is important to be able to make available methods, arrangements and uses which are technically simple to implement and to use. Thus, for example, problems arise when using special

counterstays which are arranged on the spacer, since the support capacity is relatively poor and the components are not pre-assembled but are applied by the operators or their assistants during the operation.

- 5 Using holders with mutually movable parts represents a technically complicated and awkward solution which is not compatible with practical handling and use.

The object of the invention is, inter alia, to solve these problems, and the feature which can principally be regarded as characterizing a method according to the invention is that the screw, in its position passing through the spacer, and the said spacer are first held together in a rotationally fixed manner in the holder, so that the bearing surface of the spacer protrudes beyond the holder, and the threaded part of the screw in turn protrudes beyond the bearing surface. Further features are that the rotationally fixed unit thus established by the holder, the spacer and the screw is thereafter applied to the implant in a position of cooperation of the threads of the implant and screw. The unit is then given rotating movements, during which the thread of the screw is screwed down into the thread of the implant. At a predetermined position of screwing, preferably where the cooperation between the bearing surface of the spacer and the top surface of the implant has been established, the holder is separated or detached from the spacer and the screw by means of a separating movement, for example a deflecting movement, which is preferably distinct from the rotating movement. The screw head is exposed for possible further tightening.

In one embodiment, the novel method is characterized by the fact that in order to achieve the holding function for holder, spacer and screw to form a common rotationally fixed unit, the screw is applied in the spacer to a position where its head bears against the aforementioned tightening and locking surface of the spacer, and by the fact that the spacer and screw

thus combined are thereafter pressed into an end recess in the holder, or the holder is pressed over the spacer and the screw via the said recess. In one embodiment, the holder works with an elastic and/or spring function and/or snap-in function, by means of which the spacer and the screw, in their coupled positions, are locked to the holder in the direction of rotation. While it is being screwed in, the spacer is preferably brought into cooperation with the top surface of the implant only via an annular end surface, i.e. hexagonal or other types of effective, rotation-fixing surfaces are not present in this illustrative embodiment.

The feature which can principally be regarded as characterizing an arrangement according to the invention is that before the screw is introduced into the thread of the implant, the holder supports the screw in its position passing through the spacer and supports the spacer in a rotationally fixed manner, with the bearing surface of the spacer protruding beyond the holder, and the threaded part of the screw protruding beyond the bearing surface. Further characteristics are that a rotationally fixed unit thus established by the holder, the spacer and the screw can be applied to the implant in a position of cooperation between the threads of the implant and of the screw, where screwing of the screw thread into the implant thread can be effected by means of rotating or screwing movements of the unit. A further characteristic is that the holder, in a possible screwing position, preferably where the bearing surface of the spacer cooperates with the top surface of the implant, is arranged to be separable from the spacer and the screw by means of separating movements which are preferably distinct from the rotating movement, whereupon the screw head is exposed for possible further tightening. The said separation can be effected by means of the deflection function in the holder (the present holder part).

In one embodiment of the novel arrangement, the

holder, at least in its part which can cooperate with the spacer and the screw, is made of plastic or other elastic material. The spacer and the screw, in the said coupled position, can be applied in an end recess in the said holder part receiving the screw and the spacer via a function preventing reciprocal rotating movements between spacer, screw and holder, which can be obtained from guide surfaces, a spring function, snap-in function, etc. In a further embodiment, the holder or holder part is provided with a first recess for the screw head and a second recess for securing parts on the spacer. The holder can be applied on the securing part and the screw head and secures the spacer and the screw by means of the in-built spring function and/or elasticity in the wall-supporting material of the first and second recesses, possibly in combination with a snap-in function. The holder can consist of or comprises an elongate element made of plastic or equivalent material. The holder is comparatively easily separable from the spacer and the screw, in their position applied in or firmly screwed to the implant, by means of a withdrawal movement or withdrawal movements essentially coinciding with the longitudinal direction of the implant or with a tilting movement, in which the holder disengages (for example springs aside) from the said securing part and head on the spacer or the screw. In a further embodiment, the spacer can be provided with an annular bearing surface without internal guide surfaces, for example internal guide surfaces in the form of square or hexagonal or polygonal surfaces. The holder and its attachment to the spacer and the screw can further be arranged to permit a first anchoring contact between the top surface of the implant and the bearing surface of the spacer which eliminates the risk of loosening of the implant in the bone (dentine). After the holder is detached from the spacer and the screw, the latter can be tightened for obtaining a second anchoring contact

which is effected with a force which considerably exceeds the force for the first anchoring contact. The secondary tightening function is effected in a manner known per se with a screwdriver of conventional type in this context. For the second anchoring contact, a counterstay function in the spacer can be used. For this, a tool is used which retains the spacer in a defined angular position while the screw is acted upon by the screwdriver or equivalent. The thread of the screw can be made of relatively strong material and/or coated with a friction-reducing coating for the purpose of improving the anchoring stress between spacer, screw and implant.

The thread diameter of the screw can be chosen such that it is substantially less than the diameter of the bearing surface. For example, the thread diameter of the screw can be half the diameter (mean diameter) of the bearing surface. By choosing the diameter of the screw thread and the diameter of the bearing surface and by choosing low-friction material and/or low-friction coating, the coefficient of friction is substantially lower, for example half as great at the thread as it is at the bearing surface. This means that a secure counterstay (i.e. no risk of loosening of the implant relative to the dentine) can be applied against the outside of the spacer in conjunction with the secondary tightening, despite the absence of mechanical locking via active locking surfaces between spacers and implant.

An arrangement can principally be characterized by the fact that the holder supports the spacer and the screw in a rotationally fixed manner, with the bearing surface of the space protruding beyond the holder, and with the screw extending through the spacer and protruding beyond the bearing surface via its threaded part.

The holder is preferably designed with an end recess or end recesses in which the spacer and the

screw head are pressed and held by the spring function and/or the elasticity of the holder and possibly the snap-in function. Together with the spacer and the screw, the holder forms a rotationally fixed unit which facilitates the application to the implant and the handling and delivery of the spacer and the screw.

A use according to the invention can principally be regarded as being characterized by the fact that the holder used is an elongate element which supports the spacer and the screw in their coupled position in a rotationally fixed manner, with the bearing surface of the spacer against the implant protruding beyond the holder, and the threaded part of the screw in its turn protruding beyond the bearing surface.

Further refinements of the use are characterized in that a resilient and/or elastic part of the holder is used for gripping around and securing the spacer and the screw in rotationally fixed positions in relation to the holder and to each other. The holder can also be used for transmitting manual rotational movements to the screw as the latter is screwed into the implant, i.e. as a shaft.

By means of what has been proposed above, a number of advantages are obtained which solve, inter alia, the problems set out by way of introduction. The spacer and the spacer screw can be joined together with a holder made, for example, of plastic which is clamped by means of the spring function in the holder part or snapped securely on the spacer and the screw so that these three components are held together in a simple manner. The underside of the spacer can be designed without the hexagonal socket which is generally used in this context. The underside of the spacer can thus be designed as a recess of circular cross section, which renders production much less expensive. This means that the spacer element can be rotated down to the correct position on the fixture in a much simpler way compared

to what was possible previously. The advantages of the present invention are primarily that it is now necessary to handle just one element, which can be easily designed to facilitate handling of spacer and screw as such. In addition, it is no longer necessary to depend on the spacer having to assume a rotationally correct position with respect to the implant. The holder can easily be removed and the final tightening made. If so required, a counterstay can be applied during tightening. This is often essential in order not to unnecessarily load the interface between bone and fixture so that the fixture risks being dislodged from its position. On first analysis, one may be led to believe that tightening with a counterstay is not possible because of the lack of rotational locking using hexagons or other polygons. More detailed analysis reveals that as long as the available frictional torque between fixture and spacer is greater than the frictional torque acting on the implant via the screw, i.e. the so-called thread torque, a counterstay can be applied to the spacer. The frictional torque which is transmitted to the fixture on the spacer screw depends on the tensile force in the screw, the diameter of the screw and the coefficient of friction between the screw thread and the internal thread of the fixture. The counterstay torque which can be applied depends on the clamping force between spacer and fixture which is the same as the tensile force of the screw, the diameter of the bearing surface and the coefficient of friction between the spacer and the top surface of the fixture.

Presently proposed embodiments of the method, arrangement and use having the characteristics of the invention will be described below with reference to the attached drawings, in which:

Figure 1 shows, in a side view and partial perspective view, the holder, spacer and screw in relation to an implant,

Figure 2 shows a longitudinal section through the holder, spacer and screw, in the assembled position,

Figure 3 shows a side view of the holder, screw and spacer, in the disassembled position,

Figures 4 and 4a are perspective views of the spacer, viewed obliquely from below and from above, respectively, and

Figures 5 to 6 show part of the holder in longitudinal section and enlarged.

DETAILED EMBODIMENT

In Figure 1, a holder is indicated by 1. The holder comprises an elongate part 1a and a widened part 1b arranged on the elongate part. The holder can be made of plastic material, the part 1a can be a substantially solid part and the part 1b has an end recess, in accordance with what is described below. The holder has a length L of about 20 mm and a diameter D of about 3 mm in part 1a. The part 1b has a diameter D' of about 5 mm. The parts merge into each other via a bevel 1c. Applied to the holder in a rotationally fixed manner there is a spacer 2 which protrudes beyond the end surface 1d of the holder via a part which has a bearing surface 2a. In accordance with what is described below, a screw is applied to the holder and extends through a recess in the spacer so that its threaded part protrudes beyond the bearing surface 2a. The screw is indicated by 3 and the threaded part of the screw by 3a, while the thread itself is indicated by 3b. Figure 1 also shows an implant or fixture 4 which has become firmly integrated in a bone, preferably in a symbolically indicated dentine 5. The implant or the fixture can be of a type known per se and has one or more external threads 4a. The implant is screwed into a hole 6 formed in the bone. The implant is also provided with a top surface 4b against which

the bearing surface 2a of the spacer is intended to bear when the spacer has been screwed into the implant by means of the screw 3. The implant also has an internal thread 4c with which the thread 3b of the screw can be screwed. The implant is also provided with a hexagon, by means of which the implant can be screwed down into the hole 6 formed in the dentine 5. Figure 1 shows a position 7 in which the holder has been moved into position near the implant for cooperation between the threads 3b and 4c.

In accordance with Figure 2, the spacer can be designed in a manner known per se. Thus, a bearing part 2b is included for the head 3c of the screw. The bearing recess of the part 2b for the screw head 3c is indicated by 2c. At the screw head 3c, the screw is also provided with a projecting flange or tabs 3d which cooperate with a top surface 2d of the spacer element. The part 1b of the holder is provided with an end recess 1e. The spacer 2 is introduced into this recess 1e. At the lower end, the spacer has a recess 2e. The end part 1b also has a second recess 1f in which the upper part of the screw head is introduced. The part 1b is also provided with an inwardly directed flange 1g or flange parts which can cooperate with the outside of the spacer part 2a. The spacer part 2a and the said inwardly projecting flange/flange parts are chosen so as to give a rotationally fixed anchoring for the spacer 2 in the part 1b. The recess 1f is chosen with a diameter dimension or a corresponding dimension in relation to a part 3e of the screw which projects into the recess 1f so as to give a rotationally fixed function. The recess 1f can be cylindrical or has a polygonal shape corresponding to the shape of the screw at the said inserted part 3e. The arrangement is thus such that both the spacer and the screw are given a rotationally fixed anchoring in the holder 1.

Figures 1 and 2 thus show that the holder with spacer and screw can be moved into a position of

cooperation 7 with the implant such that the thread 3b engages in the internal thread 4c. The holder can thereafter be given rotating movements 8 which function as screwing movement for the screw 3 into the implant 1 via the threads 3b and 4c. By virtue of the fact that the spacer 2 and the screw 3 are rotationally fixed in the holder 1, screwing down can continue until the lower bearing surface 2a of the spacer contacts the upper bearing surface 4b of the implant. The securing function can be designed such that the force of the rotating movement 8 is maximized and such that the screw and the spacer slip in relation to the holder when this force reaches a certain value. Risks of loosening of the implant 4 in the bone 5 with the unit are thereby eliminated. The anchoring arrangement for the spacer 2 and the screw 3 in the holder is also such that when the screw 3 has been completely or partially threaded down into the implant, the holder can be released from the completely or partially inserted screw, and the spacer fixed loosely or firmly to the screw in the longitudinal direction with a loosening force F which essentially coincides with the longitudinal axis 1h of the holder and/or with an angle of rotational force F' upon whose application the holder disengages from the spacer and the screw by deflection of the holder material. The screw head 3c is thus exposed so that the groove 3f becomes accessible for another tool, for example a conventional screwdriver.

After the holder has been released, it can be discarded. Production of the holder is relatively inexpensive by virtue of the plastic material chosen. Only part of the holder needs to be made of plastic material, i.e. the part 1b which is intended to exert elasticity movements in the securing function for the screw and the spacer. The remainder of the holder can consist of re-usable material, and known joining members can be used between the parts 1a and 1b.

Figure 3 shows the holder 1 and the spacer 2 and the screw 3 in separate positions. Upon assembly of spacer and screw in the holder (or vice versa), the screw and the spacer are joined in the position shown in Figure 2, after which application to the holder or application of the holder to spacer and screw is effected. Holder, spacer and screw are preferably supplied in the state shown in Figure 1. When screwing into the implant is effected using the holder, the latter is removed and discarded or re-used partially as described above. In Figure 3, the member 3d' fixing the longitudinal direction has the form of a solid flange extending around the screw head. Figure 3 also shows indents 2f and 2g on the spacer element, which indents can cooperate with the inwardly projecting flange 1g (Figure 2) for forming nibs or snap-locking members included in the function for fixing the angle of rotation. Figure 4 shows the annular bearing surface 2a in its entirety on the spacer 2. Figure 4 also shows the absence of internal hexagon. Such an internal hexagon normally cooperates with the hexagon 4d of the implant (cf. Figure 1). Such a hexagon or equivalent is not relevant in the present case for the reasons set out above. In Figure 4, a counterstay function is also indicated by 9, which counterstay function can be activated when the screw 3 is being tightened.

In Figures 4a and 5, the snap-in function between spacer and holder is shown in greater detail. The indents on the spacer 2 are represented by the indents 2f and 2g. In the illustrative embodiment shown, there are six such recesses. The flange 1g which is shown enlarged in Figure 5 in relation to the spacer 2 in Figure 4a can thus be made to snap down into the indents after a deflection force F' has been added to a radial deflection movement in the same direction as the application force. When the flange 1g has snapped down into the indents, the surfaces 1d and 2d on the holder 1b and spacer 2, respectively, bear on each

other. The parts 2h above the indents form nibs or snap-in members for the said flange 1g.

Figures 5 and 6 show the holder parts 1a and 1b and the recesses 1e and 1f. A radial annular surface is also indicated by 1h, which is essentially parallel to the annular end surface 1d. The surface 1h merges into the flange 1g. The wall of the recess 1f is indicated by 1k. The recesses 1e and 1f are cylindrical in the example shown.

The invention is not limited to the embodiment shown above by way of example, but can be modified within the scope of the attached patent claims and the inventive concept.

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PATENT CLAIMS

1. Method for securing a spacer (2) to a firmly
5 integrated implant (4), preferably in the jaw bone (5),
by means of a holder (1) and by means of a screw whose
threaded part will extend through a recess in the
spacer so that its thread cooperates with the thread
10 (4c) of the implant, and whose head can cooperate with
a tightening and locking surface in the spacer, which
also has a bearing surface which can cooperate with a
top surface of the implant, characterized in that the
screw (3), in its position passing through the spacer,
15 and the said spacer (2) are first held together in a
rotationally fixed manner in the holder (1), with the
bearing surface of the spacer protruding beyond the
holder, and the threaded part protruding beyond the
bearing surface, in that the rotationally fixed unit
20 thus established by the holder, the spacer and the
screw is applied to the implant in the position of
cooperation (7) of the said threads and the unit is
given rotating movements (8) during which the thread of
the screw is screwed down into the thread of the
25 implant, and in that at a predetermined position of
screwing, preferably where the cooperation between the
bearing surface of the spacer and the top surface (4b)
of the implant is established, the holder is separated
from the spacer and the screw by means of movement(s)
which is (are) preferably distinct from the rotating
30 movement, whereupon the screw head is exposed for
possible further tightening.

2. Method according to Patent Claim 1,
characterized in that to achieve the holding function
between holder (1), spacer (2) and screw (3) to form a
35 common rotationally fixed unit, the screw is applied in
the spacer to a position where its head (3c) bears
against the tightening and locking surface (2d) of the
spacer, and in that the spacer and screw thus combined

are applied in an end recess (1e, 1f) in the holder or the holder is pressed over the spacer and the screw for obtaining the rotationally fixed function.

3. Method according to Patent Claim 2, characterized in that the holder works with an elastic and/or spring function and/or snap-in function, by means of which the spacer and the screw, in their coupled position, are locked to the holder in the direction of rotation.

10 4. Method according to Patent Claim 2, characterized in that the spacer, while being screwed in by means of the screw, is brought into cooperation with the top surface (4b) of the implant only via an annular end surface (2a).

15 5. Arrangement with holder (1) for arranging a spacer on a firmly integrated implant (4), preferably in the jaw bone (5), by means of a screw (3) whose threaded part (3a) will extend through a recess in the spacer so that its thread cooperates with the thread
20 (4c) of the implant, and whose head can cooperate with a tightening and locking surface in the spacer, which also has a bearing surface (2a) which can cooperate with a top surface of the implant, characterized in that before the screw is introduced into the thread of
25 the implant, the holder supports the screw in its position passing through the spacer, and supports the spacer in a rotationally fixed manner, with the bearing surface of the spacer protruding beyond the holder (1), and the threaded part of the screw protruding beyond
30 the bearing surface, and in that a rotationally fixed unit thus established by the holder, the spacer and the screw can be applied to the implant in a position of cooperation between the threads of the implant and of the screw, where screwing of the screw thread into the
35 implant thread can be effected by means of a rotating or screwing movement (8) of the unit, and in that the holder, in a given screwing position, preferably where the bearing surface (2a) of the spacer cooperates with

the top surface of the implant, is arranged to be separable from the spacer and the screw by means of a separating movement which is preferably distinct from the rotating movement, whereupon the screw head is exposed for possible further tightening.

6. Arrangement according to Patent Claim 5, characterized in that, at least in its part (1b) which can cooperate with the spacer and the screw, the holder is made of plastic or other elastic and/or resilient material, and in that the screw and the spacer, in the said coupled position, can be applied in an end recess (1e, 1f) in the said holder part (1b) receiving the screw and the spacer via a function preventing reciprocal rotating movements between spacer, screw and holder, obtained, for example, from clamping or spring function and/or guide surfaces and/or snap-in function, etc.

7. Arrangement according to Patent Claim 5 or 6, characterized in that the holder or holder part (1b) is provided with a first recess (1f) for the screw head and a second recess (1e) for one or more securing parts (1g) on the spacer, and the holder can be applied on the securing part or securing parts and the screw head and secures the spacer and the screw by means of elasticity or resilience in the wall-supporting material of the first and second recesses.

8. Arrangement according to any of Patent Claims 5 to 7, characterized in that the holder consists of or comprises an elongate part (1a, 1b) made of plastic or equivalent material.

9. Arrangement according to any of Patent Claims 5 to 8, characterized in that the holder is comparatively easily separable from the spacer and the screw, in their position applied in or firmly screwed to the implant, by means of a withdrawal movement which essentially coincides with the longitudinal direction (1h) of the implant or with a rotating movement which is distinct from the screwing movement.

10. Arrangement according to any of Patent Claims 5 to 9, characterized in that the spacer is provided with an annular bearing surface (2a) without internal guide surfaces, for example guide surfaces in the form of squares or hexagonal surfaces.

11. Arrangement according to any of Patent Claims 5 to 10, characterized in that the holder and its attachment to the spacer and the screw are arranged to permit a first anchoring contact between the top surface of the implant and the bearing surface of the spacer which eliminates the risk of loosening of the implant in the bone (5), and, after the holder has been removed, the screw can be tightened to obtain a second anchoring contact which is effected with a force which considerably exceeds the force for the first anchoring contact.

12. Arrangement according to Patent Claim 11, characterized in that the second anchoring contact is effected by means of a counterstay function in the spacer.

13. Arrangement according to any of Patent Claims 5 to 12, characterized in that the thread of the screw is made of relatively strong material and/or is coated with a friction-reducing coating for the purpose of improving the anchoring stress between spacer, screw and implant.

14. Arrangement according to any of Patent Claims 5 to 13, characterized in that the thread diameter of the screw is substantially less than the diameter of the bearing surface and is, for example, half the last-mentioned diameter.

15. Arrangement according to Patent Claim 14, characterized in that by choosing the diameter of the screw thread and the diameter of the bearing surface and by choosing low-friction material and/or low-friction coating, the coefficient of friction is substantially lower, for example half as great, at the thread as it is at the bearing surface, which means

that a secure counterstay can be applied against the outside of the spacer upon further tightening, despite the absence of mechanical locking via active locking surfaces between the spacer and the implant.

5 16. Arrangement of a spacer (2) and a tightening screw (3) for an implant (4) for bone, preferably dentine (5), and a holder for the spacer and screw for facilitating application of the spacer and screw to the
10 implant, characterized in that the holder supports the spacer and the screw in a rotationally fixed manner, with the bearing surface (2a) of the spacer, which is intended to bear against a top surface of the implant, protruding beyond the holder, and with the screw extending through the spacer and protruding beyond the
15 bearing surface via its threaded part.

17. Arrangement according to Patent Claim 16, characterized in that the holder is designed with an end recess for the spacer and the screw head.

18. Arrangement according to Patent Claim 16 or 17,
20 characterized in that the spacer and the screw head assume rotationally fixed positions in the holder by virtue of the fact that the latter is made of resilient and/or elastic material at least at the said recess, and the holder with resilient and/or elastic function
25 cooperates with the spacer and the screw head.

19. Arrangement according to Patent Claim 16, 17 or 18, characterized in that the rotationally fixed attachment is also effected by a snap-in function and in that, for example, the spacer is designed with nibs
30 and/or indents (2f, 2g) for the said snap-in function.

20. Arrangement according to any of Patent Claims 16 to 19, characterized in that, when the spacer and screw are positioned on the implant, the holder can be separated from the spacer and the screw head for
35 longitudinal displacement in the longitudinal direction of the implant and/or a tilting movement.

21. Arrangement according to any of Patent Claims 16 to 20, characterized in that the holder, the spacer

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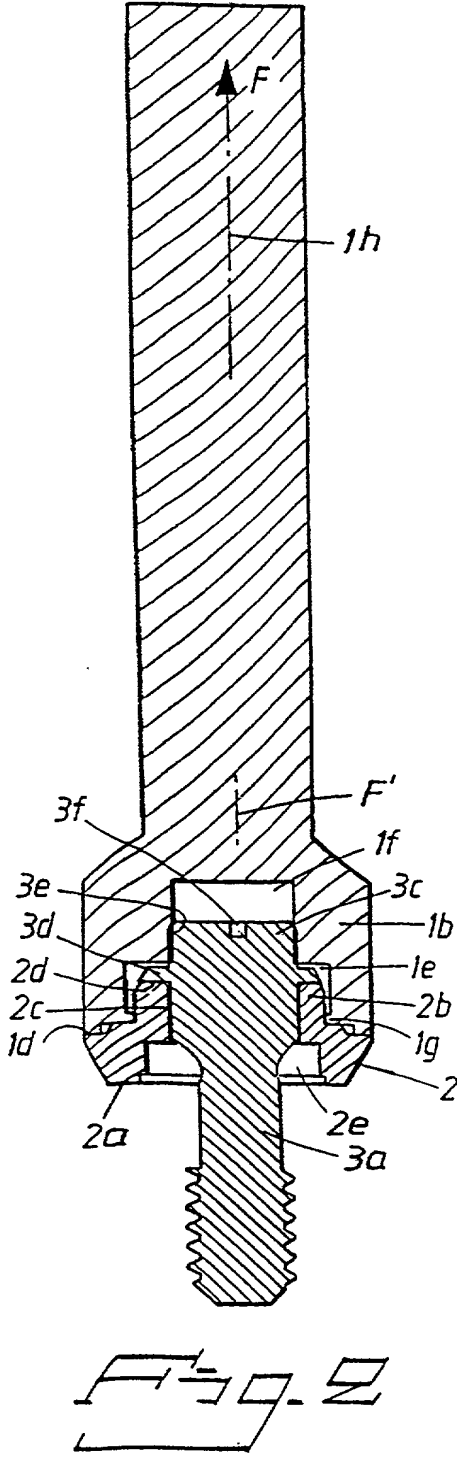
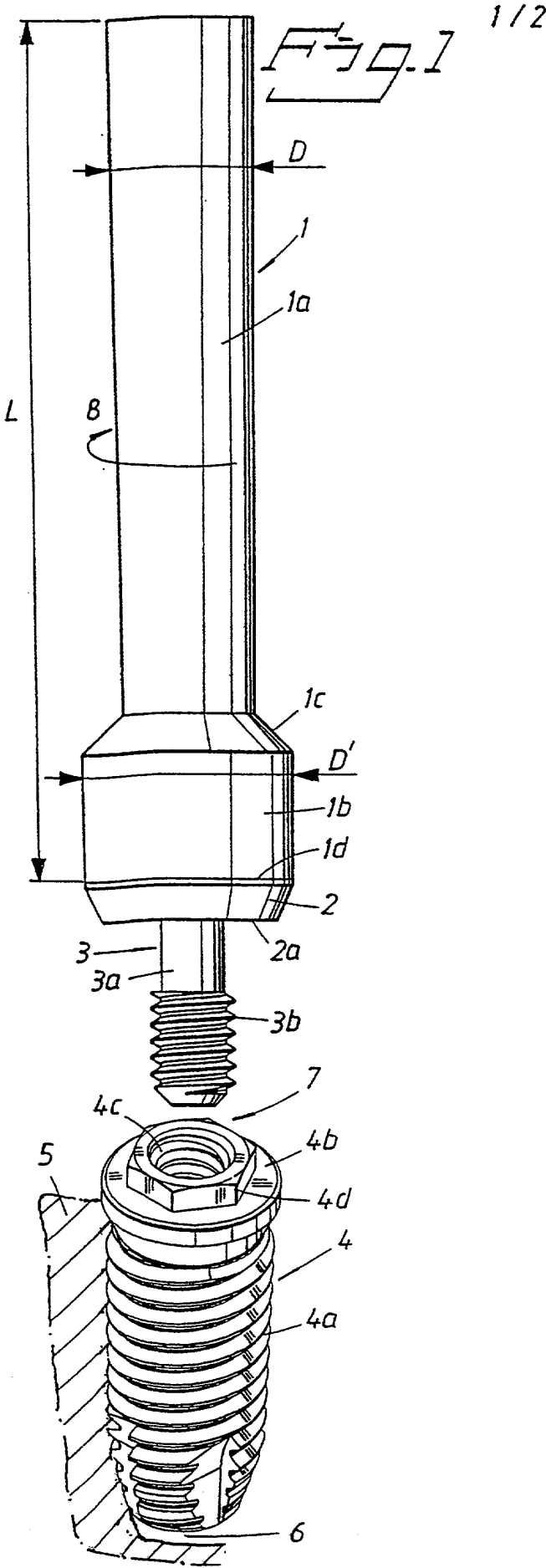
and the screw form a rotationally fixed unit, by means of which the thread of the screw can be screwed into the thread of the implant by screwing movements.

22. Use of a holder (1) for securing a spacer (2) with a screw (3) in an implant (4), characterized in that the holder (1) used is an elongate element which supports the spacer and the screw in their coupled state in a rotationally fixed manner, with the bearing surface (2a) of the spacer against the corresponding bearing surface (4b) of the implant protruding beyond the holder, and the threaded part (3a) of the screw protruding beyond the bearing surface (2a) .

23. Use according to Patent Claim 22, characterized in that a resilient and/or elastic part (1b) of the holder is used for gripping around and securing the spacer and the screw in rotationally fixed positions in relation to each other and to the holder.

24. Use according to Patent Claim 22 or 23, characterized in that the holder is used for transmitting manual rotation movements to the screw as the latter is screwed into the implant.

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Fig. 3

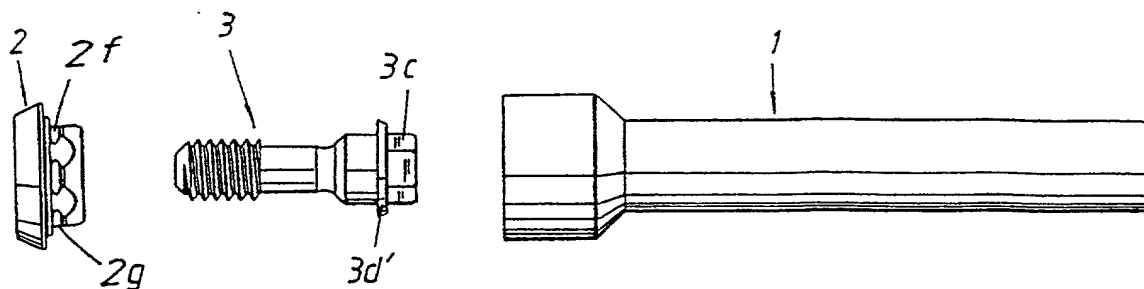


Fig. 4

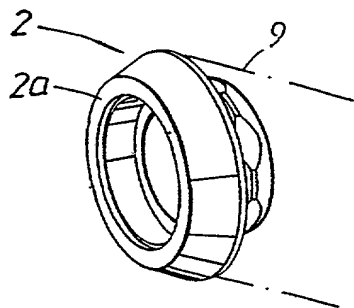


Fig. 4a

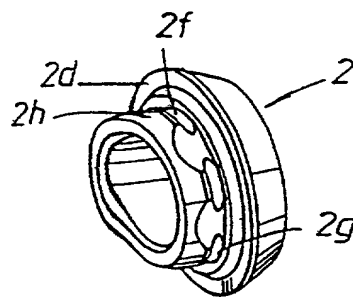


Fig. 5

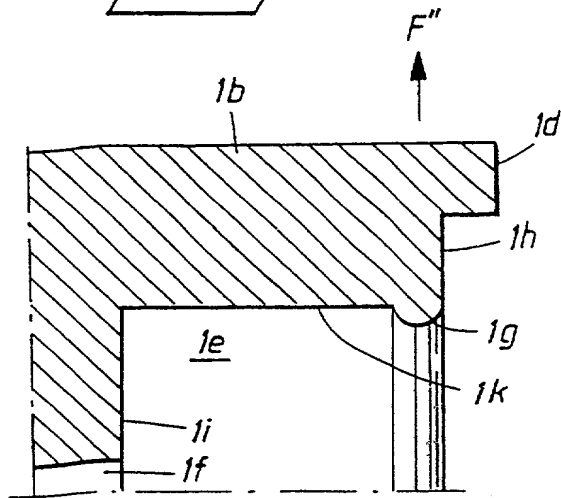
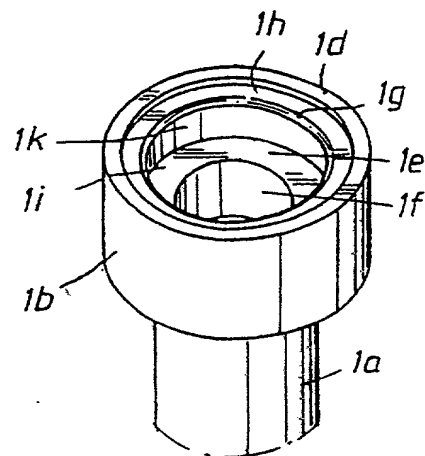


Fig. 6



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COMBINED DECLARATION AND POWER OF ATTORNEY FOR
ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL,
DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**METHOD, ARRANGEMENT AND USE FOR APPLYING A SPACER TO AN IMPLANT BY
MEANS OF A SCREW**

the specification of which

- a. ☐ is attached hereto
- b. ☒ was filed on September 18, 2001 as application Application No. 09/936,722 and was amended on _____. (if applicable).

PCT FILED APPLICATION ENTERING NATIONAL STAGE

- c. ☒ was described and claimed in International Application No. PCT/SE00/00359 filed on 24 February 2000 and as amended on _____. (if any).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56.

I hereby specify the following as the correspondence address to which all communications about this application are to be directed:

SEND CORRESPONDENCE TO: Edward A. Pennington
SWIDLER BERLIN SHEREFF FRIEDMAN, L.L.P.
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DIRECT TELEPHONE CALLS TO: Eric J. Franklin, 202-424-7500

- ☒ I hereby claim foreign priority benefits under Title 35, United States Code § 119 (a)-(d) or under § 365(b) of any foreign application(s) for patent or inventor's certificate or under § 365(a) of any PCT international application(s) designating at least one country other than the U.S. listed below and also have identified below such foreign application(s) for patent or inventor's certificate or such PCT international application(s) filed by me on the same subject matter having a filing date within twelve (12) months before that of the application on which priority is claimed:

- ☒ The attached 35 U.S.C. § 119 claim for priority for the application(s) listed below forms a part of this declaration.

Country/PCT	Application Number	Date of filing (day, month, yr)	Date of issue (day, month, yr)	Priority Claimed
Sweden	990967-2	18 March 1999		<input checked="" type="checkbox"/> Y <input type="checkbox"/> N
				<input type="checkbox"/> Y <input type="checkbox"/> N
				<input type="checkbox"/> Y <input type="checkbox"/> N

- ☐ I hereby claim the benefit under 35 U.S.C. § 119(e) of any U.S. provisional application(s) listed below.

Provisional Application No.

Date of filing (day, month, yr)

ADDITIONAL STATEMENTS FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART
OR PCT INTERNATIONAL APPLICATION(S DESIGNATING THE U.S.)

I hereby claim the benefit under Title 35, United States Code § 120 of any United States application(s) or under § 365(c) of any PCT international application(s) designating the U.S. listed below.

US/PCT Application Serial No.	Filing Date,	Status (patented, pending, abandoned)/ U.S. application no. assigned (For PCT)
US/PCT Application Serial No.	Filing Date,	Status (patented, pending, abandoned)/ U.S. application no. assigned (For PCT)

- ☐ In this continuation-in-part application, insofar as the subject matter of any of the claims of this application is not disclosed in the above listed prior United States or PCT international application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or Imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint the following attorneys and/or agents with full power of substitution and revocation, to prosecute this application, to receive the patent, and to transact all business in the Patent and Trademark Office connected therewith: Edward A. Pennington (Reg. No. 32,588), John P. Moran (Reg. No. 30,906), Eric J. Franklin (Reg. No. 37,134), Michael A. Schwartz (Reg. No. 40,161), Robert C. Bertin (Reg. No. 41,488), Alicia A. Meros (Reg. No. 44,937), Chadwick A. Jackson (Reg. No. 46,495), Edward J. Naidich (Reg. No. 43,826), and Sean O'Hanlon (Reg. No. 47,252) of Swidler Berlin Shereff Friedman having an address of 3000 K Street, N.W., Suite 300, Washington, D.C. 20007-5116.



I hereby authorize the U.S. attorneys and/or agents named hereinabove to accept and follow instructions from Eric L. Franklin as to any action to be taken in the U.S. Patent and Trademark Office regarding this application without direct communication between the U.S. attorneys and/or agents and me. In the event of a change in the person(s) from whom instructions may be taken I will so notify the U.S. attorneys and/or agents named hereinabove.

Full name of sole or first inventor Lars Jörneus

Inventor's signature*



date *January 11, 2002*

Residence: Riabergsvägen 7B, S-430 30 Frillesås, Sweden

Citizenship: Swedish

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* Before signing this declaration, each person signing must:

1. Review the declaration and verify the correctness of all information therein; and
2. Review the specification and the claims, including any amendments made to the claims.

After the declaration is signed, the specification and claims are not to be altered.